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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,962

12/03/2003

David Ernest Hartley

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COOK GROUP PATENT OFFICE

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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

04/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/726,962	Applicant(s) HARTLEY ET AL.	
	Examiner KATHERINE M. DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2007 has been entered.
2. Claims 28-34 are currently pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The first line of the claim recites "a deployment device" and prosthesis in combination. However, the claim recites "the prosthesis being mounted on **a** deployment device" in line 2. It is unclear if the deployment device in combination with the prosthesis is the deployment device upon which the prosthesis is mounted. Please use a different term to differentiate the deployment devices or correct the antecedent basis.

Furthermore, regarding claim 28, lines 23-24 recite "central portion of the prosthesis is releasably mounted to the manipulator on the deployment catheter". It is unclear if the central portion is releasably mounted to the previously recited "manipulator" or if the central portion is releasably mounted to a manipulatable portion of the deployment catheter. For the purposes of examination, the Examiner interpreted the language as the central portion releasably mounted to the manipulator of the deployment *device*.

5. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "the barbs" and "the uncovered stent". There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

6. Applicant's arguments with respect to claims 28-34 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andreas et al. (US 7,147,656) in view of Hartley et al. (US 6,939,370). Regarding claims 28 and 31-33, Andreas et al. disclose the device substantially as claimed including a tubular prosthesis (30) with the distal end including at least one self expanding stent (col 2, ln 27-39). The prosthesis is everted with the proximal and distal ends extending towards the distal end of the deployment device, the central portion extending proximally, and the proximal end within the distal end (Fig 2A). The proximal end of the prosthesis is capable of being surgically fastened to the adjacent and around the aortic heart valve and the distal end is capable of extending into the descending aorta. The deployment device comprises a central catheter (36) with a nose cone, or distal end; a deployment catheter (34) coaxially around the central catheter; and a manipulator (32) coaxially around the deployment catheter. The device comprises means to lock the movement of the deployment catheter with respect to the central catheter, as seen in Figs 2A-2B when the deployment catheter and central catheter are advanced forward together with respect to the manipulator (col 5, ln 8-10). The central portion of the prosthesis is releasably mounted to the manipulator, the proximal end of the prosthesis is fastened to the distal end of the deployment catheter, and the distal end of the prosthesis is fastened to the nose cone dilator (Figs 2A-2C).

However, Andreas et al. do not disclose the nose cone includes means to retain the distal end of the prosthesis with the assistance of a trigger wire. Hartley et al. disclose a similar deployment device and prosthesis combination (Fig 2). Hartley et al. teach the deployment device comprises a trigger wire arrangement to maintain the prosthesis in the retracted position during advancement to the deployment site (col 4, In 12-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Andreas et al. to include a trigger wire to more securely hold the prosthesis in place about the deployment device in a retracted position during advancement to the desired site within the patient's vasculature.

Regarding claim 29, Andreas et al. do not disclose a portion of the prosthesis, or self expanding stent, is covered. Hartley et al. disclose a similar prosthesis (col 5, In 47-53) with one portion comprising a covered self expanding stent (27) and another portion comprising an uncovered self expanding stent (29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Andreas et al. to include a cover for a distal portion of the prosthesis, thereby enhancing the interface between the prosthesis and the inner vessel wall.

Regarding claim 30, Andreas et al. do not disclose the uncovered self expanding stent of the prosthesis comprises barbs. Hartley et al. teach the uncovered portion of the prosthesis may include barbs (col 6, In 1-2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

device of Andreas et al. to include barbs to securely position the prosthesis in place and prevent undesired migration of the prosthesis after implantation.

Regarding claim 34, Andreas et al. disclose a central catheter (36) and the distal end of the central catheter may be interpreted to be a nose cone. However, Andreas et al. do not disclose the nose cone is in the form of a proximally opening capsule. Hartley et al. teach a central catheter with a nose cone (3) that has a proximally opening capsule. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nose cone of Andreas et al. to include a proximally opening capsule such that the stenosed area may be more easily traversed during the delivery state in which the prosthesis is in the contracted condition retained against the nose cone.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Katherine Dowe
March 31, 2008

/K. M. D./
Examiner, Art Unit 3734